

STATEMENT OF WORK

A. BACKGROUND AND OBJECTIVES

The Drug Synthesis and Chemistry Branch (DSCB) of the Developmental Therapeutics Program (DTP) of the Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) is seeking support services to operate and maintain the National Cancer Institute's Chemotherapeutic Agents Repository (NCI-CAR). The principal goals of this contract is 1) to support compound acquisition activities related to the DTP anticancer pre-clinical drug evaluation program which seeks to identify new small molecule therapeutic agents and 2) distribution of chemicals to intramural and extramural investigators for research purposes. The primary tasks of the contract are the receipt, registration, storage, analysis, arraying and distribution of small molecules and purified natural products. In addition, a lesser number of compounds from other NIH (e.g. NIAID, NEXT, NCATS) programs may be handled through this contract.

This contract is also responsible for providing an informational interface with NCI and external investigators that are submitting or requesting research compounds; for updating of the chemical database which includes chemical, inventory, receiving and shipping information; systematic file and record keeping of both current and archival information related to Repository activities; and reacquisition of samples for continued chemical and biological studies.

The program is highly flexible and the Contractor shall have the flexibility to respond to changing Program priorities.

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Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below.

SPECIFIC TASKS

TASK 1. Acquisition/Documentation

- a. Execute registration policies and procedures developed by DTP for the submission of structures, associated chemical data and compound samples using the DTP website: <http://dtp.nci.nih.gov/>. These procedures may be revised and updated over time. This includes the assignment of NSC registration numbers to chemical structures and other entities (e.g. biologics, creams, investigational, ethical and OTC drug products) using policies and procedures developed by DSCB.
- b. Maintain and execute procedures for the non web-based manual submission and registration of structures, associated chemical data and the compounds.
- c. Act as primary point-of-contact for submitters of compounds requesting NCI60 evaluation. It is estimated that 6,000-8,000 requests for individual compounds will be received annually.
- d. Assist investigators on structure and sample submission, and website registration procedures. The procedures and policies are described at the DSCB website: http://dtp.cancer.gov/docs/misc/common_files/submit_compounds.html.

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- e. Input chemical structures and chemical data into the NCI chemical database. The majority of structures (6,000-8,000 annually) are submitted by investigators requesting anti-cancer testing. It is anticipated that this number along with related labor costs will decrease 5-10% per year.
- f. Check the chemical accuracy of structures and chemical data entered into the database. This includes checking an additional ~5,000 designated archival structures annually for accuracy.
- g. Maintain permanent files of all supplier correspondence related to submission of structures, chemical data and physical compound samples. This includes a file of legal confidentiality agreements between NCI and investigators.
- h. Reacquire compounds from submitters as requested by the Contracting Officer's Representative (COR). Generally, this material will be used for additional in vitro/in vivo evaluation.
- i. Acquire, through purchase order process, additional quantities of commercial compounds as requested by the COR.
- j. Distribute copies of requested archival documentation to NCI staff and external investigators as directed by the COR. These may be as hard copies or in electronic form.
- k. Maintain relevant, accurate, and current records such as identity, inventory and shipping history, for all registered compounds.

TASK 2.

Receipt and Storage

- a. Store chemicals, purified natural products and bulk compounds. This includes approximately 500,000-600,000 individual samples in current long-term storage. The majority of compounds are in amounts ranging from 5 mg to 20 g, with a few samples of bulk drug up to 50 kg. It is estimated that ~90% of samples are stored at controlled ambient conditions.
- b. Receive weekday chemical sample shipments and related documentation and, safely store until registered and moved to permanent storage or shipped to researchers.
- c. Store chemicals, drugs and plated sets under their recommended storage conditions. This includes capabilities for temperature storage at controlled, ventilated ambient (5,000 ft²), 0-5 deg C (5,000 ft³), -15 to -20 deg C (10,000 ft³), and -70 to -80 deg C (500 ft³). In addition, the capability to store a limited number of samples under nitrogen or argon atmosphere; protected from light; under controlled humidity conditions.
- d. Provide sufficient monitoring of storage conditions to guarantee continuous proper storage including, for a limited number of bulk API samples, adequate monitoring and documentation to meet cGMP guidelines. Back-up systems and plans should be available to maintain proper storage conditions in the event of loss of power or other emergency for a period of 5 days.
- e. Notify COR immediately when physical changes in chemical samples are noticed.
- f. Provide safe storage and security measures to conform to all pertinent drug/chemical regulations. This includes an adequate waterless fire suppression system to protect staff, the chemical inventory and storage infrastructure.

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- g. Prepare generic Material Safety Data Sheets for specific compounds as directed by COR.
- h. Maintain the current computerized inventory of compounds of interest and bulk drugs in the repository. In addition, infrequently requested drugs shall be inventoried for accuracy at the time an order request is filled.
- i. Provide for the safe and proper disposal of items to be eliminated from the inventory stock as the result of decomposition or for other reason at the request of the COR. No samples should be disposed without authorization of the COR.
- j. Receive returned chemicals and drugs and return to inventory or dispose.
- k. All work shall be performed utilizing good laboratory techniques in accordance with accepted industry standards.

TASK 3. Shipping and Distribution

- a. Weigh, package and ship chemicals and drugs as approved by the COR to NCI screening laboratories and external research investigators. These may be located domestically or internationally (e.g. Europe, Asia, Australia). Shipping costs will be covered by the requester. It is expected 25,000-30,000 samples will be weighed annually.
- b. Provide special handling and packaging for heat and/or light sensitive and labile chemicals and drugs. The shipments shall conform to all laws and regulations, both domestic and international, governing the shipping of hazardous substances and other regulated substances.
- c. Furnish shipping cartons, cushioning materials, labels, containers, insulating material, dry ice and any other supplies to insure the safe, intact arrival of the contents of each package shipped. It is expected that there will be 400 shipments to NCI in Frederick, MD annually. The contractor will be responsible for both shipping costs and packaging costs. In addition, it is expected that there will be 700 ambient shipments and 500 dry-ice shipments to extramural investigators, annually. The contractor will only be responsible for packaging costs to extramural investigators.
- d. Update inventory transactions, document the shipment of compounds, and associated data to the NCI chemical database.
- e. Provide for regular (3-4/week) overnight shipments of samples to the NCI testing and screening laboratories in Frederick, MD. Include provisions for 1-day turnaround for a limited number of expedited shipments.

TASK 4. Plating Operations

- a. Array selected compounds in 96-well plates. Plates will generally be generated using DMSO solvent. Employ appropriate methods to preclude absorption of water both while generating and storing plates (e.g. inert atmosphere conditions). Maintain government provided plating robotic apparatus in good working condition.
- b. Create mother plates and replicate copies of plated compound sets for distribution to investigators as needed. It is anticipated that ~75 mother plates will be produced and ~2,000

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replicate plates annually. The sets include a Structural Diversity Set of ~1,600 samples, a Mechanistic Diversity Set of ~820 compounds, and an Approved Oncology Drug Set of ~120 compounds. The generation of additional diverse and focused plated sets may be requested by the COR as determined by Program needs.

- c. Store DMSO plated sets (-20 to -25 deg C.) until distribution is requested.
- d. Receive, document and store, prior to distribution, plated libraries from outside investigators and institutions.
- e. Capability to operate in 96-well and 384-well environments.
- f. Appropriately package and ship DMSO plated compounds to investigators. Packaging and shipping methods should be selected to maintain integrity of plates and their contents. In general, this requires insulated shipping containers containing dry-ice or cool packs. Shipping costs will be covered by the requester.
- g. Maintain the capability to ship packages to all countries worldwide.

TASK 5. Analytical Testing

- a. The Contractor should have the capability to provide analytical data on a limited number of samples. This should include standard analytical methods to determine chemical structure and purity (e.g. elemental analysis, IR, ¹H NMR, ¹³C NMR, MS and LC/MS). The specific test required will be directed by the COR.
- b. The turnaround time for analyses should not exceed 5 working days.

TASK 6. Security and Safety

- a. The Contractor shall not divulge any information concerning the suppliers, chemicals and drugs received, stored, or shipped except to authorized personnel as indicated by the COR. All other inquiries should be directed to the COR.
- b. It is anticipated that the contractor will have access to sensitive information under this project. The contractor shall guarantee strict confidentiality of the information/data that it is provided during the performance of the contract through the use of non-disclosure agreements. Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.
- c. The Contractor shall comply with all pertinent security and safety requirements required by applicable Federal, State and local government regulations.
- d. Personnel assigned to the project shall be bonded.
- e. The chemical storage areas shall be protected from fire damage by systems other than water sprinklers.

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f. The Contractor shall be the authorized waste disposal agent for work performed under this contract and comply with all local, State and Federal regulations.

g. The Contractor shall provide appropriate and adequate safeguards to insure for the safety and security of all Government-owned property including but not limited to, chemical inventory, laboratory equipment, computers and hard copy, film and electronic information. Back-up systems and plans should be available to maintain proper storage conditions for all inventory in the event of loss of power or other emergency for a period of 5 days. The Contractor shall maintain all Government-owned equipment in good working order.

h. The Contractor shall provide appropriate and adequate safeguards to insure for the safety and security of all Government-owned property which is removed by the Contractor's employees from the Contractor's facility (e.g. hard copy documents, laptops, compact discs, flash memory devices).

i. The Contractor shall conform to all applicable NIH policies in regards to Internet and computer security and training (e.g. firewalls, virus protection, password protection, encryption, etc.).

TASK 7. Expansion of Repository Services

At the direction of the Contracting Officer per the issuance of a Task Order, the contractor shall provide additional repository and related services in support of the NCI mission. At the discretion of the NCI, additional Task Orders may be established for repository and/or related services as outlined in the above Task 1 through Task 6. Storage capacity for these services is in addition to the number of samples specified in Task 2 and the specific amount of space will be defined at the Task order level. These services could comprise portions of Tasks 1 through 6 as delineated in a separate Task Order Statement of Work as well the identification of specific deliverables.

C. PERSONNEL QUALIFICATIONS

a. The Contractor shall describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment and programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

b. The Contractor shall provide resumes of all key personnel required. Each resume must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

c. The Contractor shall describe the education, training, relevant experience (including a background in the understanding of chemical structures, chemical reactivity, chemical hazards, safety procedures, regulatory requirements, domestic and international shipping procedures) suitability and availability of each of the following:

1) Project Director/Manager

The Project Director/Manager should be trained in an appropriate discipline with at least a Bachelor's degree from an accredited school with ideally ten years relevant experience, or with a Master's degree with ideally seven years' experience in areas relevant to this work and include

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supervisory or managerial level responsibilities. List the name of the Project Director/Manager responsible for overall implementation of the contract and key contact for technical aspects of the project. Discuss the qualifications, experience, and accomplishments of the Project Director/Manager. State the estimated time to be spent on the project, their proposed duties, and the areas or phases for which they will be responsible.

2) Acquisitions/Documentation Manager

List all other Professional personnel, including separately the Acquisitions/Document Manager, who will be participating in the project. Discuss their qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3) Support Staff, including provisions for IT-related support staff

List all other Support Staff, who will be participating in the project. Discuss their qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

4) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for employment, or on a subcontract or consultant basis. This should include information technology personnel who will support work performed under the contract. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. Commitment letters for use of consultants and other personnel to be hired must include the following items:

- The specific items or expertise provided.
- Availability to the project and the amount of time anticipated.
- Handling of rights to publications and intellectual property consistent with the Bayh-Dole Act.

D. TRANSITION: TRANSITION PLAN/PHASE-IN/PHASE-OUT

The transition plan is to define the required activities and to lay out a schedule as to how the current organization will transition to a new contractor.

TRANSITION PLAN

All locations for the repository will be considered that can efficiently complete the tasks outlined in the Statement of Work. All offerors must provide a plan for overnight hard copy transfer of documents to DTP staff in Rockville, MD along with overnight shipment of packaged chemicals to NCI collaborators within the Frederick and Bethesda, MD corridor.

Commitments for occupancy of a proposed facility shall be in place at the time of proposal submission which meets all required Federal, state and local requirements and certifications for compound storage, handling,

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shipping (both US and international), distribution, plating, disposal, and security requirements. Those commitments must demonstrate and support a fully operational facility within 30 days after contract award.

If a new location and facility is proposed for the repository, the offeror shall address relocation logistics of all designated chemical samples and associated documentation and equipment from their current location in Germantown, MD to the new location.

A pre-Award Site Visit shall be conducted, at the discretion of the Government, to verify the offeror's ability to meet the Government's requirements for the repository. For any new facility proposed for the repository, the offeror must address in their transition plan how the complete move of all materials and equipment will be accomplished in less than 60 days after the effective date of contract award.

Offerors proposing on a new facility and location for the repository must address the following in their Transition Plan. Offerors shall provide in a separately tabbed section of the technical proposal, labeled Transition Plan, a detailed plan for moving the work from its present location to the proposed new location which includes:

1. A timeline to establish a fully functional facility. The time line shall be divided into the following minimum functions: equipment transfer, storage functionality, chemical collection transfer, information systems functionality, data transfer, acquisition functionality, distribution/shipping functionality, plating functionality. Offerors shall demonstrate in their transition plan, a timely, efficient and effective transition with particular importance on safe relocation and shipping of chemical compounds.
2. A thorough discussion of safeguards for prevention of damage or loss, in whole or in part, of the chemical collection during transfer, protection of temperature, light and moisture sensitive materials, handling of damaged items and insurance coverage. The transition plan must address the safe packaging, transport and set- up of Government provided equipment (e.g. computers, hoods, balances, refrigerators, freezers, etc.) the use of multiple shipments, and any other considerations that the offeror determines to be critical.
3. A thorough discussion of the offeror's capabilities, experience and planning in integrating external data and platforms (e.g. NCI) into their operations.
4. A thorough discussion of all required Federal, state and local approvals for the transport and in-transit storage of required materials including, but not limited to, cytotoxic agents and other hazardous materials. A summary of the required approvals should also be provided in table form along with copies of available documentation.
5. A thorough discussion of all Federal, state and local approvals, licenses, certificates, permits and –other legal requirements necessary for the establishment of the facility and contents, at the proposed location and for the proposed use and term of the contract. These shall be in place at the time of the proposal submission. A summary of the required approvals should also be provided in table form along with copies of available documentation.
6. A commitment for lease of the proposed facility for the term of the contract or evidence of ownership of the facility shall be presented.

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7. The cost for the transition plan shall not be included in the technical proposal. The cost for the transition plan shall be included in the business proposal as a separate tab. The transition budget shall be a separate budget from the offeror's total cost proposal.
8. For budgeting purposes, it is estimated that the current facility contains 550,000 containers. A standard container is a 2-8 dram glass vial. It is estimated that 95% of the inventory is stored in these vials, although larger quantities up to several kilos are stored in larger containers. For purposes of cost estimates, assume all compounds are stored in 4 gram glass vials along with 25 1-kg containers. Also, assume that cold transport conditions equivalent to the cold space estimate in Section C (6) above will be required.

Phase-In

The incumbent Contractor shall assist the successful contractor in the transition of this contract. The transition period shall consist of the final 60 calendar days of the current contract. On the 61st calendar day, the successful contractor shall assume all responsibilities. The following shall apply only to a transition wherein the incumbent contractor is not the successful contractor.

- a) The incumbent Contractor shall provide the successor with detailed briefings regarding the organization, maintenance, storage and transfer of the chemical inventory, the equipment inventory, structure of the database tables, software and procedures required for continuing maintenance and operation of systems developed under this contract. The briefing should include relevant safety information regarding the chemical inventory.
- b) The incumbent Contractor shall transfer all project materials, to include but not limited to, the chemical inventory, government-owned equipment, any customized computer programs (e.g., statistical simulations), project materials, documentation, operating manuals, etc. to the successor Contractor upon direction from the Contracting Officer and in a manner prescribed by the Contracting Officer Representative (COR). Transfer shall be completed by the expiration date of the contract and shall include provision by the incumbent Contractor of accurate and complete inventory and data files and pertinent documentation.
- c) The incumbent Contractor shall transfer the files and documentation for all databases developed on this contract to the successor Contractor. Transfer shall be completed by the expiration date of the contract.
- d) For a contractor other than the incumbent a detailed plan and timetable for implementing the transition shall be provided by the new Contractor and shall be accomplished prior to the effective date of the contract.

Phase-Out

At the conclusion of this effort, the Contractor shall assist in the transition of this contract to a successor contractor. The transition period shall consist of the final 60 calendar days of the contract. On the 61st calendar day, the successor shall assume all responsibilities. The following shall apply only to a transition wherein the contractor is not the recipient of the successor award.

- a) The incumbent Contractor shall provide the successor with detailed briefings regarding the organization, maintenance, storage and transfer of the chemical inventory, the equipment inventory, structure of the database tables, software and procedures required for continuing

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maintenance and operation of systems developed under this contract. The briefing should include relevant safety information regarding the chemical inventory.

- b) The incumbent Contractor shall transfer all project materials, to include but not limited to, the chemical inventory, government-owned equipment, any customized computer programs (e.g., statistical simulations), project materials, documentation, operating manuals, etc. to the successor Contractor upon direction from the Contracting Officer and in a manner prescribed by the Contracting Officer Representative (COR). Transfer shall be completed by the expiration date of the contract and shall include provision by the incumbent Contractor of accurate and complete inventory and data files and pertinent documentation.
- c) The incumbent Contractor shall transfer the files and documentation for all databases developed on this contract to the successor Contractor. Transfer shall be completed by the expiration date of the contract.
- d) The Contractor shall provide a detailed plan and timetable for implementing the transition from the incumbent contractor to the successful contractor. This shall be accomplished prior to the effective date of the contract.